FILED UNDER SEAL - CONTAINS CONFIDENTIAL INFORMATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MYLAN INC. and MYLAN PHARMACEUTICALS INC., **Plaintiffs,** **v.** **SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, SMITHKLINE BEECHAM P.L.C., SB PHARMCO PUERTO RICO, INC., APOTEX INC., and APOTEX CORPORATION,** **Defendants.**	**Civil Action No. _____** **FILED UNDER SEAL**

VERIFIED COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Mylan Inc., formerly known as Mylan Laboratories, Inc., and Mylan Pharmaceuticals Inc. (collectively, "Mylan"), for their complaint against SmithKline Beecham Corporation, doing business as GlaxoSmithKline, Smithkline Beecham P.L.C., SB Pharmaco Puerto Rico Inc. (collectively, "GSK") and Apotex, Inc. and Apotex Corporation (collectively, "Apotex"), hereby allege as follows:

I. THE PARTIES

1. Plaintiff Mylan Inc. is a corporation organized under the laws of Pennsylvania having a place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

2. Plaintiff Mylan Pharmaceuticals Inc. is a corporation organized under the laws of West Virginia having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26504.

3. Upon information and belief, Defendant SmithKline Beecham Corporation, doing business as GlaxoSmithKline, is a Pennsylvania corporation having its principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania 19102.

4. Upon information and belief, Defendant SmithKline Beecham P.L.C. is a public limited company organized under the laws of England and Wales with its principal place of business at 980 Great West Road, Brentford, Middlesex, TW89GS, England.

5. Upon information and belief, Defendant SB Pharmaco Puerto Rico Inc. is a company organized and existing under the laws of Puerto Rico with its principal place of business at State Road No. 172, Km. 9.1/Bo. Certenejas, Cidra, Puerto Rico, 00739.

6. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada and has its principal place of business at 150 Signet Drive, Ontario, Canada, M9L IT9.

7. Upon information and belief, Defendant Apotex Corporation is a corporation organized and existing under the laws of the State of Delaware, and has its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

II. NATURE OF THE ACTION

8. This is a civil action for breach of contract against GSK for the breach of a Patent License and Settlement Agreement (the "Agreement") (attached as Exhibit A) it entered into with Mylan under which Agreement Mylan has the exclusive right to make, have made, sell, have sold and import generic paroxetine hydrochloride extended-release tablets, subject to two limited exceptions. The instant Action also avers against Apotex for Apotex's willful inducement of GSK to breach the Agreement. Upon information and belief, Apotex knew or should have known of the Agreement and Mylan's exclusive rights therein. Nevertheless, upon

information and belief, Apotex entered into discussions with GSK with the purpose and intent to induce GSK to breach the Agreement by allowing Apotex to enter the generic paroxetine hydrochloride extended-release tablet market by obtaining rights to sell GSK's branded product as a generic (an "Authorized Generic"). Apotex, upon information and belief, successfully induced GSK to breach the Agreement, and in so doing also tortiously interfered with the Agreement itself. Upon information and belief, GSK breached the Agreement by working with Apotex in violation of the exclusivity provisions of the Agreement, when Apotex meets none of the criteria required for the exceptions set forth in the Agreement.

III. JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C § 1331, this being a civil action arising under the laws of the United States; and 28 U.S.C. § 1332, because the amount in controversy exceeds seventy-five thousand dollars ($75,000.00) exclusive of interest and costs, and is between citizens of different States.

10. Upon information and belief, GSK is registered to do business in New Jersey. In addition, GSK sells products and does business throughout the United States, including within this judicial district. Furthermore, the Agreement between Mylan and GSK designates the United States District Court for the District of New Jersey as the location for resolving disputes regarding the Agreement. Thus, by virtue of this Agreement GSK has submitted to the jurisdiction of the United States District Court for the District of New Jersey. This court has personal jurisdiction over GSK by virtue of the above-referenced facts.

11. Upon information and belief, Apotex is registered to do business in New Jersey and/or conducts business in New Jersey. In addition, Apotex sells products and does business throughout the United States, including within this judicial district. Upon information and belief,

Apotex has submitted to the jurisdiction of the United States District Court for the District of New Jersey. This court has personal jurisdiction over Apotex by virtue of the above-referenced facts.

IV. THE AGREEMENT BETWEEN MYLAN AND GSK

12. GSK markets and sells Paxil CR®, the brand name for paroxetine hydrochloride extended-release oral tablets in strengths of 12.5 mg, 25 mg and 37.5 mg, approved for the treatment of major depressive disorder.

13. On June 26, 2007, GSK sued Mylan for infringement of U.S. Patent No. 7,229,640 ("the '640 patent"), stemming from Mylan's filing of an Abbreviated New Drug Application ("ANDA") directed to a generic version of Paxil CR®. That lawsuit, Civil Action No. 07-2939, was filed in this Court and was assigned to the Honorable Joel A. Pisano, who later facilitated settlement discussions between the parties.

14. Due in part to Honorable Joel A. Pisano's involvement in settlement discussions between the Parties, on October 19, 2007, GSK and Mylan stipulated to the dismissal of all claims with prejudice.

15. On October 22, 2007, the Court entered the aforementioned stipulation. (D.E. 39)

16. Negotiations between GSK and Mylan led to the Agreement at issue in the instant Action, which was entered into by and between GSK and Mylan on August 10, 2007. Section II(c) of the Agreement set forth that the patent licenses set forth therein (providing Mylan a license under the '640 patent to "make, have made, sell, have sold and import Mylan Generic Paroxetine Products") "shall be exclusive (even to GSK) in favor of Mylan for all Generic Paroxetine Products."

17. On September 14, 2007, GSK and Mylan entered into a First Amendment to the Agreement (the "First Amendment").

18. On September 27, 2007, GSK and Mylan entered into a Second Amendment to the Agreement (the "Second Amendment"), which slightly modified Mylan's exclusivity rights under the Agreement. Pursuant to the Second Amendment at Section 2, Mylan retained exclusivity rights to the patent licenses except in two instances:

a. "If GSK receives a Third Party Notification and GSK initiates an action for patent infringement, GSK can enter into a settlement agreement with respect to such action at any time and Mylan agrees to waive its exclusivity under Section II(c) in order to permit GSK under such settlement agreement to grant such Third Party a non-exclusive license under the GSK Patents to sell Generic Paroxetine Product(s) in the dosage form(s) specified in the Third Party's ANDA, on which the Third Party Notification is based, effective as of 180 days after the date on which Mylan launches Generic Paroxetine Products for sale in the Territory.

b. Also, GSK or its Affiliate may commence marketing and selling generic paroxetine hydrochloride controlled or modified release products pursuant to its Paxil ® CR NDA ("Authorized Generic Products") at the end of the second year after Mylan launches its Generic Paroxetine Products."

19. Therefore, Mylan's license remains exclusive unless and until the following two scenarios occur: Scenario (1): a third party, such as Apotex, (a) files an ANDA for generic paroxetine hydrochloride extended-release tablets containing paragraph IV and/or section viii statements with respect to all unexpired patents listed in the Orange Book as covering GSK's Paxil CR®, (b) GSK sues that ANDA filer, and (c) GSK and the third party enter into a settlement agreement on only the dosage forms covered in the ANDA; or Scenario (2): GSK or an Affiliate launches an Authorized Generic ("AG") under its New Drug Application directed to Paxil CR®. Furthermore, should scenario (1) occur, GSK was required to provide Mylan with immediate notice of the third party's ANDA filing. *See* Exhibit A, Section II, paragraph (a).

20. On October 23, 2007, Mylan issued a world-wide press release (a press release that remains freely and publicly available at Mylan's website) that Mylan had entered into a patent license and settlement agreement noted above with GSK "relating to Paroxetine Hydrochloride (HCl) Extended-Release (ER) Tablets, the generic version of GSK's Paxil CR®."

21. Specifically, Mylan announced that "under the Agreement...Mylan is provided patent licenses and the right to market all three strengths of Paroxetine HCL ER tablets, 12.5 mg, 25 mg and 37.5 mg, beginning no later than October 1, 2008."

22. In a subsequent press release dated May 14, 2008 Mylan announced that it has "launched Paroxetine Hydrochloride (HCl) Extended-release (ER) Tablets, the generic version of GlaxoSmithKline's (GSK) Paxil CR®."

V. MYLAN'S SALE OF GENERIC PAROXETINE HYDROCHLORIDE EXTENDED-RELEASE PRODUCTS

23. In accordance with the Agreement, Mylan launched generic paroxetine hydrochloride extended-release tablets in mid-May, 2008.

24. Since May, 2008, the generic paroxetine hydrochloride tablets product has been an important component of Mylan's portfolio of drug products, and one of Mylan's most successful products in the United States.

25. Since May, 2008, Mylan's generic paroxetine hydrochloride tablets have generated hundreds of millions of dollars in sales in the United States.

26. Since May 2008, Mylan is and has been the ***only*** company lawfully offering generic paroxetine hydrochloride extended-release oral tablets to the public.

27. Accordingly, Mylan has the entire generic market share for generic paroxetine hydrochloride extended-release oral tablets, and the introduction of an unlawful competitor

would irreparably damage Mylan's exclusive market share, and be at odds with its prior settlement with GSK.

VI. APOTEX UNLAWFULLY TORTIOUSLY INTERFERES WITH AND INDUCES GSK TO BREACH THE AGREEMENT

28. Upon information and belief, Apotex, in concert with GSK, will unlawfully launch all three strengths of paroxetine hydrochloride extended-release capsules, pursuant to GSK's NDA, an Authorized Generic, on or about September 20, 2010.

29. Mylan became aware of this fact through information received from a customer. This customer informed Mylan that Apotex was offering for immediate sale generic paroxetine as the Authorized Generic.

30. Mylan thereafter discovered, on the website for Daily Med (http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=23484), labels for Apotex's Authorized Generic, which labels make clear that GSK is manufacturing the Authorized Generic in dosages of 12.5 mg, 25 mg and 37.5 mg for Apotex, upon information and belief, pursuant to rights granted to Apotex by GSK.

31. Upon information and belief, Apotex has not filed an ANDA for generic paroxetine hydrochloride extended-release tablets containing a paragraph IV certification and/or section viii statements with respect to the patents listed in the Orange Book as covering GSK's Paxil CR®. Moreover, should Apotex have filed an ANDA for generic paroxetine hydrochloride extended release tablets, pursuant to Section II, paragraph (a) of the Agreement, GSK was required to give Mylan notice of Apotex's ANDA, which GSK did not do.

32. Upon information and belief, GSK has instituted no lawsuit against Apotex for the development, manufacture, sale, or intent to sell generic paroxetine hydrochloride extended-release tablets.

33. Upon information and belief, Apotex is not and has not at any point been an Affiliate of GSK.

34. Therefore, upon information and belief, Apotex meets *none* of the criteria necessary to meet one of the exceptions to the exclusivity portions of the Agreement, as modified by the Second Amendment.

35. Upon information and belief, GSK is allowing and intends to allow Apotex to develop, manufacture, sell, have sold, and distribute generic paroxetine hydrochloride extended-release tablets, in violation of the Agreement and the amendments thereto.

36. Upon information and belief, Apotex knew and/or should have known of the Agreement between GSK and Mylan, and yet knowingly and willfully took action to enter the market for generic paroxetine hydrochloride extended-release tablets, interfering with Mylan's exclusivity for same.

37. Upon information and belief, despite knowing of the Agreement between Mylan and GSK, Apotex has taken direct actions in order to induce GSK to violate the Agreement and interfere with the exclusivity for generic paroxetine hydrochloride extended-release tablets held by Mylan and to interfere with the Agreement for its own profit.

38. Upon information and belief, Apotex entered into discussions with GSK to manufacture, develop, distribute, sell or offer for sale generic paroxetine hydrochloride extended-release tablets, despite Apotex's knowledge that Mylan is the only permitted manufacturer, developer, distributer and seller of generic paroxetine hydrochloride extended-release tablets.

39. Upon information and belief, these discussions, among other things, resulted in GSK breaching the Agreement with Mylan.

40. Apotex and GSK's actions are causing Mylan to suffer irreparable harm by the improper loss of its exclusivity in the generic market, including irretrievable loss of market share and customers of the generic paroxetine hydrochloride extended-release tablets. As the sole, lawful holder of the market share, should Mylan lose the exclusivity to Apotex for the generic market of paroxetine hydrochloride extended-release tablets, the result would harm Mylan and is beyond compensable in monetary terms.

VII. FIRST CAUSE OF ACTION: BREACH OF CONTRACT AS AGAINST GSK

41. Plaintiffs repeat and reiterate the allegations contained within Paragraphs 1 through 40 above as if set forth fully herein.

42. Mylan and GSK entered into a valid Agreement on August 10, 2007, together with the subsequent amendments to the Agreement.

43. Mylan has at all times complied with its responsibilities and requirements under the Agreement and its amendments.

44. Upon information and belief, by willfully and intentionally allowing, and/or working with Apotex in order to manufacture and distribute generic paroxetine hydrochloride extended-release tablets, and in the absence of conditions meeting any of the exclusivity exclusions provided in the Second Amendment, GSK is in breach of the Agreement.

45. Moreover, to the extent that Apotex filed an ANDA with the FDA for generic paroxetine hydrochloride extended-release tablets, GSK was required, under Section II, paragraph (a) of the Agreement, to provide Mylan with notice of Apotex's ANDA. Thus, to the extent that Apotex filed an ANDA, GSK is also in breach of the Agreement for failure to provide required notice to Mylan.

46. GSK's breach of the Agreement and the amendments thereto has and will cause irreparable harm to Mylan, including irretrievable loss of market share and customers of the generic paroxetine hydrochloride extended-release tablets. As the sole valid holder of the market share, should Mylan lose the exclusivity to Apotex for the generic market of paroxetine hydrochloride extended-release tablets, the result would be harmful to Mylan and beyond compensable in monetary terms.

VIII. SECOND CAUSE OF ACTION: INDUCEMENT TO BREACH CONTRACT AS AGAINST APOTEX

47. Plaintiffs repeat and reiterate the allegations contained within Paragraphs 1 through 45 above as if set forth fully herein.

48. In the time since entering into the Agreement, Mylan has successfully marketed, sold, manufactured and distributed generic paroxetine hydrochloride extended-release tablets in dosages of 12.5 mg, 25 mg and 37.5 mg, and this product has become among one of Mylan's most successful.

49. Upon information and belief, Apotex knew of Mylan and GSK's business relationship.

50. Upon information and belief, Apotex knew or should have known that Mylan and GSK entered into the Agreement and amendments thereto, which Agreement provided for Mylan's exclusive rights to the generic paroxetine hydrochloride extended-release tablets.

51. Upon information and belief, despite knowing of Mylan and GSK's business relationship, the Agreement, and that Mylan has certain exclusive rights to the generic paroxetine hydrochloride extended-release tablets, Apotex intentionally entered into discussions with GSK in an attempt to enter into the generic paroxetine hydrochloride extended-release tablet market,

causing GSK to breach the Agreement with Mylan and irreparable harm to Mylan and its market share. Apotex's actions are without justification or excuse.

52. Upon information and belief, Apotex's entry into the generic paroxetine hydrochloride extended-release tablet market does not fit within either of the exclusivity exclusion criteria set out in the Second Amendment to the Agreement.

53. Mylan has and will suffer irreparable damages due to Apotex's inducement of GSK to breach the Agreement, including irretrievable loss of market share and customers of the generic paroxetine hydrochloride extended-release tablets. As the sole, lawful holder of the market share, should Mylan lose the exclusivity to Apotex for the generic market of paroxetine hydrochloride extended-release tablets, the result would be harmful to Mylan and beyond compensable in monetary terms.

VIII. THIRD CAUSE OF ACTION: TORTIOUS INTERFERENCE WITH THE AGREEMENT

54. Plaintiffs repeat and reiterate the allegations contained within Paragraphs 1 through 52 above as if set forth fully herein.

55. Upon information and belief, Apotex knew of Mylan and GSK's business relationship.

56. Upon information and belief, Apotex, in spite of its knowledge of Mylan and GSK's business relationship and the Agreement, willfully and intentionally took actions intended to interfere with the business relationship, causing GSK to breach the Agreement.

57. Upon information and belief, Apotex's entry into the generic paroxetine hydrochloride extended-release tablet market does not fit within either of the exclusivity exclusion criteria set out in the Second Amendment to the Agreement.

58. Upon information and belief, Apotex's actions are without justification or excuse.

59. Mylan has and will suffer irreparable damages due to Apotex's interference with the business relationship between Mylan and GSK and causing GSK to breach the Agreement, including irretrievable loss of market share and customers of the generic paroxetine hydrochloride extended-release tablets. As the sole valid holder of the market share, should Mylan lose the exclusivity to Apotex for the generic market of paroxetine hydrochloride extended-release tablets, the result would be harmful to Mylan and beyond compensable in monetary terms.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

a. That GSK has breached the Agreement, causing harm to Mylan;

b. That Apotex has willfully and knowingly induced GSK to breach the Agreement;

c. That Apotex has intentionally and tortuously interfered with Mylan's Agreement with GSK;

d. That Apotex, its officers, agents, servants and employees and those persons in active concert or participation with any of them, are temporarily restrained and preliminarily and permanently enjoined from commercially manufacturing, developing, distributing, selling or offering for sale a generic paroxetine hydrochloride extended-release tablets;

e. That GSK, its officers, agents, servants and employees and those persons in active concert or participation with any of them, are temporarily restrained and preliminarily and permanently enjoined from from supplying Apotex with paroxetine hydrochloride extended-release tablets;

f. That Mylan be awarded appropriate monetary relief if Apotex, its officers, agents, servants or employees or those persons in active concert or participation with any of them commercially manufacture, develop, distribute, sell or offer for sale generic paroxetine hydrochloride extended-release tablets;

g. That any generic paroxetine hydrochloride extended-release tablets manufactured, developed, distributed, sold or offered for sale by Apotex be recalled;

h. That Mylan be awarded monetary damages;

i. That Mylan be awarded its attorneys' fees and costs;

j. That Mylan be awarded treble damages.

k. That Mylan be awarded such other and further relief as this Court deems just and proper;

l. That GSK's actions be found to be willful; and

m. That Apotex's actions be found to be willful.

IX. CERTIFICATION PURSUANT TO L.CIV.R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matters in controversy are not subject of any other action pending in any other court or of any pending arbitration or administrative proceeding.

X. DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury for all the issues so triable.

Dated: September 20, 2010

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Respectfully submitted,

MYLAN INC. and
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